

REMARKS

Claims 51, 53, 54, 59 and 68-77 are pending in this application. Claims 51, 53, 56, 59 and 68-74 are amended herein.

In the Advisory action, the Examiner indicates that in the amendments proposed on October 21, 2003, the amendment to the final clause of the claims conflicts with the recitation of the prior steps where comparisons are made between malignant and normal or benign (not “and” as recited in the amended portion of the claims.) Accordingly, the claims are amended here to revise the recitation “comparing the calculated ratio of the amounts measured in ... with a corresponding predetermined ratio from a reference fluid sample originating from a living body having, a normal thyroid or a benign thyroid” to --comparing the calculated ratio of the amounts measured in ... with corresponding predetermined ratios from a reference fluid sample originating from a living body having a normal thyroid and a reference fluid sample originating from a living body having a benign thyroid--. This amendment clarifies that comparison is made to normal thyroid and to benign thyroid reference samples and provides consistency with the latter clauses of the claims. Applicants submit that the specification clearly provides support for this amendment.

For example, on page 27, lines 5-8, the specification discusses the ratio of Tg(s) not bound to Con A related to the total Tg(s) in a sample from papillary carcinoma, relative to those “in the sample from benign disease such as benign thyroid adenoma, Grave’s disease, follicular adenoma or thyroid adenoma.” This is clearly a reference to comparison to separate samples from different people having these diseases, which would inherently involve obtaining “a reference fluid sample

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originating from a living body having a benign thyroid". The specification discloses this in numerous places.

Similarly, page 31, lines 8-12, discuss "extracts from benign thyroid adenoma tissue, Graves' disease tissue and normal thyroid tissue" which are compared to an extract from papillary carcinoma. Again, this description clearly inherently involves reference fluid samples as recited in the present claims.

In the Advisory action, the Examiner states that the amendment in the Response under 37 CFR 1.116 of August 21, 2003, raises new issues of new matter because the specification fails to provide support for methods where the deduced ratio is higher or lower than a reference normal ratio and also higher or lower than a reference benign ratio.

Applicants respectfully submit that the specification does provide support for this amendment, in particular on page 27, lines 9 to 18; page 31, lines 8 to 18; page 32, line 22 to page 33, line 1, page 33, bottom line to page 34, line 8 of the specification.

For example, on page 27, lines 9 to 11, the ratio of Tg not bound to Con A related to the amount of total Tg in sample from the follicular carcinoma (malignant disease) is significantly higher than those in the sample from follicular adenoma (benign disease) and significantly higher than those in the sample from a normal. That is, the sample is determined to be malignant when the calculated ratio is significantly higher than that of the reference fluid sample of the follicular adenoma (benign) **and** that of the reference fluid sample of the normal thyroid. The other cited portions of the specification are similar in this regard.

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Applicants therefore respectfully request reconsideration of the outstanding rejections in view of the amendments to the claims and Applicants' remarks in the Response dated August 21, 2003.

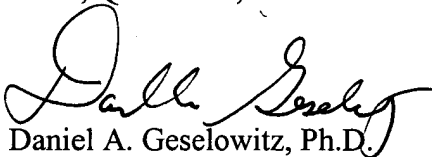
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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicants undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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